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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,468	07/30/2003	Nils Holmstrom	P03,0233	9181
26574	7590	09/13/2007		
SCHIFF HARDIN, LLP PATENT DEPARTMENT 6600 SEARS TOWER CHICAGO, IL 60606-6473				
			EXAMINER MORALES, JON ERIC C	
			ART UNIT 3766	PAPER NUMBER
			MAIL DATE 09/13/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/630,468	<b>Applicant(s)</b> HOLMSTROM, NILS	
	<b>Examiner</b> Jon-Eric C. Morales	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 7/30/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 5-6, 13-14, 17-18, 25, 28-29, and 32-33 is rejected under 35 U.S.C. 102(b) as being anticipated by Renirie et al. (US Patent No. 5741211).

Regarding claims 1, 13, 25, and 28, Renirie discloses a controlling system (circuit), a electrode lead sensor adapted to sense blood insulin/glucose (constituent) connected to the control system via a lead, another electrode lead sensor for sensing electrical activity of the heart, both are implanted into the patients heart. The control circuit identifies first and second portions of the same heart cycle and determining blood insulin levels occurring at first portion of the cycle and also determining a second blood insulin level occurring at a second portion of the cycle. The control circuit emits and output signal indicative of functioning of the heart dependent on a relation between first and second value (column 2 lines 63-68, column 3 lines 50-55, column 4 lines 41-45, column 5 lines 57-60, column 6 lines 11-17, column 7 lines 52-54). Regarding claims 2, 5, 14, 17, 29, and 32, Renirie discloses the first value is detected during the T-wave (atrial diastole occurs) and the second value is detected during the QRS (ventricular systole occurs) (column 7 lines 52-54). Concerning claims 6, 18 and 33, Renirie discloses monitoring device comprises a therapeutic device adapted to execute cardiac

therapy of delivering insulin into the blood upon the occurrence selected from the group consisting of the first value and second value fulfilling a predetermined condition (column 4 lines 55-65).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3, 15, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Renirie et al. (US Patent No. 5741211). Renirie discloses the claimed invention except for detecting the second value in said second portion with a final 70% of said diastolic portion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to detect the second value in said second portion with a final 70% of said diastolic portion, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

5. Claims 4, 7-9, 16, 19-21, 26, 31, and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Renirie et al. (US Patent No. 5741211) as applied to claims 1, 6, 18, 28, and 33 above, and further in view of Obel (US Patent No. 5199428). Renirie discloses the invention substantially as claimed however does not show blood constituent being blood oxygen first value being lower than a first predetermined level and a second value being higher than a second predetermined level, the first value

decreasing by more than a first predetermined amount and the second value decrease less than a second predetermined amount over a plurality of heart cycles. Obel discloses sensing blood oxygen and blood pH levels (column 3 lines 42-47). Obel also discloses predetermined conditions having the pH value fall below the rate of change of the pH threshold (lower first value) as well as the blood oxygen falling above a rate of change of blood oxygen threshold (higher second value) all occurring over a plurality of heart cycles (column 7 lines 26-45). The pH and blood oxygen levels having these threshold values allows for control of the stimulation pulses (cardiac therapy) (column 9 lines 25-39) being delivered to the heart (column 8 lines 55-56). Therefore it would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify the device of Renirie by adding stimulation of the heart as therapy treatment, controlled by sensed blood oxygen and blood pH level thresholds as taught by Obel in order to facilitate controlled cardiac therapy.

6. Claims 10, 22 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Renirie et al. (US Patent No. 5741211) as applied to claims 1, 13 and 28, and further in view of Hill et al. (US 2002/0107553). Renirie discloses the invention substantially as claimed however does not show the therapeutic device having a drug delivery to a person whom heart-monitoring devices implanted. Hill discloses a drug delivery system included within the implanted device that may be used together with the electrical stimulation. This drug delivery system provides biologically active agent to the tissues of patients to prevent anticipated or detected physiological insults. Therefore it would have been obvious to one of ordinary skill in the art, at the time of the invention,

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to modify the device of Renirie by adding rug delivery system as taught by Hill in order to prevent anticipated or detected physiological insults to the patient.

7. Claims 11, 12, 23, 24, 38, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Renirie et al. (US Patent No. 5741211) as applied to claims 1, 13 and 28 above, and further in view of Jensen et al. (US Patent No. 6752765). Renirie discloses the invention substantially as claimed however does not show the implantable monitoring device having a warning signal generator and a physical activity level sensor. Jensen discloses the use of an activity sensor such as an accelerometer or a piezoelectric transducer that can be used to verify if the patient is at rest or not (column 5 lines 8-15). This will help to regulate the pacing therapies being delivered to the patient. Also Jensen discloses the system having an alarm or indicator (warning signal) that is triggered so the clinician maybe alerted when the patient's condition changes. Therefore it would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify the device of Renirie by adding a activity sensor and a alarm signal as taught by Jensen in order to facilitate the regulation of pacing therapies being deliver to a patient and to be able to signal the clinician when the patient's condition changes.

### ***Response to Arguments***

8. Applicant's arguments with respect to claim1-39 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon-Eric C. Morales whose telephone number is 571-272-3107. The examiner can normally be reached on Monday through Friday from 8am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

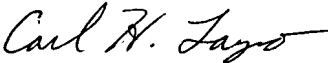
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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